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09/738,212

CASE TX/4-118-8353B



FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

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December 2, 2005

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT OF

NEUER ET AL.

U.S. PATENT NO: 6,951,841B2

ISSUED: OCTOBER 4, 2005

FOR: PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR

CYCLOSPORINE WITH A POLYETHOXYLATED SATURATED HYDROXY

FATTY ACID

Mail Stop Petition Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF FINAL PATENT TERM ADJUSTMENT DETERMINATION UNDER 37 CFR §1.705(d)

Sir:

The final patent term adjustment for U.S. Patent No. 6,951,841B2 issued on October 4, 2005 was determined by the PTO to be 527 days which according to the PAIR system was calculated based on the total number of days due to PTO delay, 659 days, less the total number of days due to Patentees' delay, 132 days. Copies of the cover page of U.S. Patent No. 6,951,841B2 and the patent term adjustment history printout from the PAIR system are attached hereto. In making this determination, it appears that the PTO in calculating the total number of days due to PTO delay considered the Board of Patent Appeals and Interferences (BPAI) decision favorable (reversed) when in fact the BPAI decision was unfavorable. A detailed review of the file history of this patent revealed that the patent term adjustment of 527 days was incorrect and that the correct patent term adjustment should be 76 days. Patentees respectfully request that the patent term adjustment be revised to 76 days. The bases for this correction is indicated below.

37 CFR §1.702(b) indicates that the term of a patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the application was filed under 35 U.S.C. §111(a), but not including any time consumed by review by the BPAI. In the present case, the three year period as measured from the application filing date of December 15, 2000 ended on December 15, 2003, however, any days that were consumed by review by the BPAI before December 15, 2003 cannot be included in measuring the three year period and must be added onto the projected issue date of December 15, 2003. The total number of days consumed by the BPAI as determined from the Notice of Appeal dated August 16, 2002 to the BPAI decision dated November 10,

12/06/2005 CNGUYEN1 00000042 190134 6951841

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2004 is 451 days. Accordingly, the addition of 451 days from December 15, 2003 results in an adjusted

patent issue date of March 10, 2005.

The patent actually issued on October 4, 2005. Thus, the total number of days of patent term

adjustment due to PTO delay as measured from the adjusted issue date of March 10, 2005 to the actual issue date of October 4, 2005 is 208 days.

With respect to 37 CFR §1.704(b), the PAIR system correctly indicated a reduction of patent term

adjustment of 132 days due to Patentees' delay as measured from the three-month period from the date of the Office Action of July 18, 2001 to the Patentees' Response received February 27, 2002.

Accordingly, Patentees are entitled to receive a final patent term adjustment of 76 days as determined

from 208 days due to PTO delay less 132 days due to Patentees' delay.

It is further noted that U.S. Patent No. 6,951,841B2 is subject to a terminal disclaimer over copending Application Ser. No. 09/547,802 (the '802 application). The PAIR system indicated that as of

November 9, 2005 the '802 application is on appeal awaiting decision of the BPAI.

In view of the foregoing, it is respectfully requested that this Request for Reconsideration be favorably considered and that the PTO send out a Certificate of Correction wherein the cover page of the

subject U.S. patent reflects a final patent term adjustment of 76 days.

Please charge the \$200 fee required by 37 CFR §1.18(e) and any other fees that may be required to Deposit Account No. 19-0134 in the name of Novartis Corporation. An additional copy of this Request for Reconsideration of Final Patent Term Adjustment is enclosed.

Respectfully submitted,

Novartis Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080 (862) 778-7859

Attorney for Applicants

wantes

Reg. No. 37,350

Attachs.: cover page of U.S. Patent No. 6,951,841B2

Copy of PAIR printout

Extra copy of Request of Reconsideration of Final Patent Term Adjustment

postcard

Date: December 2, 2005

PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR CYCLOSPORINE WITH A

POLYETHOXYLATED SATURATED HYDROXY-FATTY ACID

'atent Term Adjustment History

Patent Term Adjustment (PTA) for Application Number: 09/738,212								
		Days						
12-15-2000	USPTO Delay (PTO):	659						
10-04-2005	Three Years:	-						
	Applicant Delay(APPL):	132						
	Total PTA:	527						
	Explanation Of Calculations	8						
	12-15-2000 10-04-2005 +0 +0	12-15-2000 USPTO Delay (PTO): 10-04-2005 Three Years: +0 Applicant Delay(APPL): +0 Total PTA:						

Post-Issue Petitions (days): +0	Pre-Issu	e Petitions (days): +0	Applicant Delay(APPL): 132		132			
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03-26-2003 Mail Reply Brief Noted by Examiner	03-26-2003	Mail Reply Brief Noted by Exa	miner		<u> </u>			
03-24-2003 Reply Brief Noted by Examiner	03-24-2003	Reply Brief Noted by Examiner	ŗ	企				



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03-06-2003	Date Forwarded to Examiner	<u>^</u>	
03-06-2003	Case Docketed to Examiner in GAU	仓	
02-24-2003	Reply Brief Filed	t	
01-15-2003	Mail Examiner's Answer	个	
01-13-2003	Examiner's Answer to Appeal Brief	个	
	Date Forwarded to Examiner	仓	
10-16-2002	Appeal Brief Filed	*	
08-16-2002	Notice of Appeal Filed	个	
08-16-2002	Request for Extension of Time - Granted	个	
	Mail Final Rejection (PTOL - 326)	命	
05-20-2002	Final Rejection	ົ	,
03-15-2002	Date Forwarded to Examiner	仓	
02-27-2002	Response after Non-Final Action	仓	132
	Request for Extension of Time - Granted	仓	仓
01-31-2002	Case Docketed to Examiner in GAU	Ŷ	Ŷ
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07-18-2001	Mail Non-Final Rejection	企	仑
07-16-2001	Non-Final Rejection	仓	
06-09-2001	Date Forwarded to Examiner	4	
06-06-2001	Response to Election / Restriction Filed	命	
	Request for Extension of Time - Granted	Ŷ	
	Information Disclosure Statement (IDS) Filed	t r	
	Mail Restriction Requirement	會	
	Requirement for Restriction / Election	4	
04-13-2001	Information Disclosure Statement (IDS) Filed	仓	
04-09-2001	Information Disclosure Statement (IDS) Filed	Ŷ	
04-03-2001	Case Docketed to Examiner in GAU	4	
02-27-2001	Application Dispatched from OIPE	•	
	Correspondence Address Change	Ŷ	
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	IFW Scan & PACR Auto Security Review	1	
	Preliminary Amendment	仓	
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